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Docket No. 241331US20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Patricia B HOYER, et al.

SERIAL NO: 10/650,799

FILED: August 29, 2003

FOR: ANIMAL MODEL FOR PERIMENOPAUSE AND MENOPAUSE AND METHODS OF INDUCING OVARIAN FAILURE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.


Respectfully submitted,

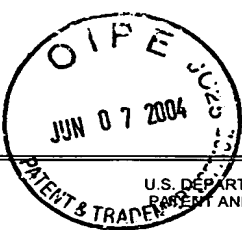
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Form PTO 1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY DOCKET NO.
241331US20SERIAL NO.
10/650,799

LIST OF REFERENCES CITED BY APPLICANT

APPLICANT
Patricia B. HOYER, et al.FILING DATE
August 29, 2003GROUP
1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	6,107,540	08/22/00	Sawyer et al			
	AB	6,583,334	06/24/03	Haslam			
	AC						
	AD						
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AO					
	AP					
	AQ					
	AR					
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	Miriam J.J. de Kleijn et al.; "Endogenous Estrogen Exposure and Cardiovascular Mortality Risk in Postmenopausal Women"; American Journal of Epidemiology, Vol. 155, No. 4, pp. 339-345; 2002	
	AX	Caren G. Solomon et al.; "Menstrual Cycle Irregularity and Risk for Future Cardiovascular Disease"; The Journal of Clinical Endocrinology & Metabolism, 87(5), pp. 2013-2017; 2002	
	AY	Frank B. Hu, MD et al.; "Age at Natural Menopause and Risk of Cardiovascular Disease"; Arch Intern Med/Vol 159, pp. 1061-1066; May 24, 1999	
	AZ	Francine Grodstein et al; "A Prospective, Observational Study of Postmenopausal Hormone Therapy and Primary Prevention of Cardiovascular Disease"; Annals of Internal Medicine, Vol. 133, No. 12; pp. 933-941; December 19, 2000	<input checked="" type="checkbox"/> Additional References sheet(s) attached

Examiner

Date Considered

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. 241331US20	SERIAL NO. 10/650,799
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AAA	Francine Grodstein et al; "Postmenopausal Hormone Use and Secondary Prevention of Coronary Events in the Nurses' Health Study"; Annals of Internal Medicine; Vol. 135, No. 1, pp. 1-8; July 3, 2001		
AAB	Frank B. Hu, MD et al.; "Postmenopausal Hormone Therapy and the Risk of Cardiovascular Disease: The Epidemiologic Evidence"; The American Journal of Cardiology; Vol. 90(1A), pp. 26F-29F; July 3, 2002		
AAC	NIH: Postmenopausal Hormone Therapy Information; http://www.nih.gov/PHTindex.htm ; 4pp.		
AAD	Karin H. Humphries et al; "Risks and benefits of hormone replacement therapy: The evidence speaks"; Canadian Medical Association, 168(8), pp. 1001-1010; April 15, 2003		
AAE	Gail A. Laughlin et al; "Hysterectomy, Oophorectomy, and Endogenous Sex Hormone Levels in Older Women: The Rancho Bernardo Study"; The Journal of Clinical Endocrinology & Metabolism"; Vol. 85, No. 2, pp. 645-651; 2000		
AAF	Manuel Neves-e-Castro et al; "Results from WHI and HERS II - Implications for Women and the prescriber of HRT"; Maturitas 42 (2002) 255-258		
AAG	Bjarne K. Jacobsen et al' "Age at Natural Menopause and All-Cause Mortality: A 37-Year Follow-up of 19/731 Norwegian Women"; American Journal of Epidemiology, Vol. 157, No. 10, pp. 923-929; 2003		
AAH	Sally A. Shumaker, Ph.D. et al; "Estrogen Plus Progestin and the Incidence of Dementia and Mild Cognitive Impairment in Postmenopausal Women The Women's Health Initiative Memory Study: A Randomized Controlled Trial"; JAMA, Vol. 289, No. 20 (Reprinted), pp. 2651-2662; May 28, 2003		
AAI	Peter P. Zandi, Ph.D. et al.; "Hormone Replacement Therapy and Incidence of Alzheimer Disease in Older Women The Cache County Study"; JAMA, Vol. 288, No. 17, pp. 2123-2129; November 6, 2002		
AAJ	Susan M. Fontaine et al; "Stereochemical Aspects of Vinylcyclohexene Bioactivation in Rodent Hepatic Microsomes and Purified Human Cytochrome P450 Enzyme Systems"; DMD, Vol. 29, No. 2, pp. 179-184; 2001		
AAK	S.M. Borman et al; "Ovotoxicity in Female Fischer Rats and B6 Mice Induced by Low-Dose Exposure to Three Polycyclic Aromatic Hydrocarbons: Comparison through Calculation of an Ovotoxic Index"; Toxicology and Applied Pharmacology, Vol. 167, pp. 191-198; 2000		
AAL	Patricia B Hoyer et al; "Ovarian Toxicity of 4-Vinylcyclohexene Diepoxide: A Mechanistic Model"; Toxicologic Pathology, Vol. 29, No. 1, pp. 91-99; 2001		
AAM	Patricia B. Hoyer et al; "Assessment of Follicle Desruction in Chemical-Induced Ovarian Toxicity"; Annu. Rev. Pharmacol. Toxicol., Vol. 36, pp. 307-331; 1996		
AAN	Loretta P. Mayer et al; "Long-term effects of ovarian follicular depletion in rats by 4-vinylcyclohexene diepoxide"; Reproductive Toxicology, Vol. 16, pp. 775-781; 2002		
AAO	Stephen B. Hooser et al; "Long-Term Ovarian and Gonadotropin Changes in Mice Exposed to 4-Vinylcyclohexene"; Reproductive Toxicology, Vol. 8, No. 4, pp. 315-323; 1994		
AAP	Bill J. Smith et al; "The Role of Epoxidation in 4-Vinylcyclohexene-Induced Ovarian Toxicity"; Toxicology and Applied Pharmacology, Vol. 105, pp. 372-381; 1990		
AAQ	L.N. Springer et al; "Involvement of Apoptosis in 4-Vinylcyclohexene Diepoxide-Induced Ovotoxicity in Rats" Toxicology and Applied Pharmacology, Vol. 139, pp. 394-401; 1996		
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	AAA	P.J. Devine et al; "Ultrastructural Evaluation of Oocytes During Atresia in Rat Ovarian Follicles"; Biology of Reproduction, Vol. 63, pp. 1245-1252; 2000					
	AAB	Xiaoming Hu et al; "Expression and Redistribution of Cellular Bad, Bax and Bcl-X _L Protein Is Associated with VCD-Induced Ovotoxicity in Rats"; Biology of Reproduction, Vol. 65, pp. 1489-1495; 2001					
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	AAG	Lori Mosca, MD et al; "Cardiovascular Disease in Women A Statemtn for Healthcare Professionals From the American Heart Association"; Circulation, Vol. 96, No. 7, pp. 2468-2482; October 7, 1997					
	AAH	Suzanne Oparil; Supplement to Hypertension; Arthur C. Corcoran Memorial Lecture; "Hormones and Vasoprotection"; Journal of the American Heart Association, Vol. 33, No. 1, Part II; January 1999					
	AAI	Stephen Hulley, MD et al; "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women"; JAMA, Vol. 280, No. 7, pp. 605-613; August 19, 1998					
	AAJ	Dr. Anderson et al; "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women"; JAMA, Vol. 288, No. 3, pp. 321-333; July 17, 2002					
	AAK	David W. Purdie; "Consequences of long-term hormone replacement therapy"; British Medical Bulletin, Vol. 56, No. 3, pp. 809-823; 2000					
	AAL	Carmen Rodriguez, MD, MPH et al; "Estrogen Replacement Therapy and Ovarian Cancer Mortality in a Large Prospective Study of US Women"; JAMA, Vol. 285, No. 11, pp. 1460-1465; March 21, 2001					
	AAM	Francis L. Bellino, Ph.D.; "Nonprimate Animal Models of Menopause: Workshop Report"; Menopause: The Journal of the North American Menopause Society, Vol. 7, No. 1, pp. 14-24; 2000					
	AAN	Howard L. Judd, MD; "Hormonal Dynamics Associated with the Menopause"; Clinical Obstetrics and Gynecology, Vol. 19, No. 4, pp. 775-788; December 1976					
	AAO	Jodi A. Flaws et al; "Destruction of Preantral Follicles in Adult Rats By 4-Vinylcyclohexene Diepoxide"; Reproductive Toxicology, Vol. 8, No. 6, pp. 500-514; 1994					
	AAP	Shao-Wen Kao et al; "Early Effects of Ovotoxicity Induced By 4-Vinylcyclohexene Diepoxide in Rats and Mice"; Reproductive Toxicology, Vol. 13, No. 1, pp. 67-75; 1999					
	AAQ	Gregory F. Erickson; Menopause Biology and Pathobiology; "Ovarian Anatomy and Physiology"; Chapter 2, pp. 13-31; 2000					
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	AAA	Cheryl A. Dyer, Ph.D., Alzheimer's Association, KRS: Application form for Individual Research Project, Project Title: Apo E isoform effect on perimenopausal ovarian steroids and risk for AD					
	AAB	Patricia B. Hoyer, Research Plan, Grant Application, PHS 398/2590, pp. 17-47.					
	AAC	Loretta P. Mayer, Grant Proposal, AIM III, p. 25.					
	AAD	Loretta P. Mayer et al., Preprint of an article entitled "The Follicle-Depleted Mouse Ovary Produces Androgen					
	AAE	Loretta P. Mayer et al., July 2001 Presentation to the Ottawa Society for Study of Reproduction, "Long-Term Effects of Ovotoxicity in Rats Exposed to 4-Vinylcyclohexene Diepoxide.					
	AAF	Loretta P. Mayer et al., Abstract and Poster Presentation, "An ovary-intact mouse model that mimics peri-menopause in women", Published after September 20, 2002.					
	AAG	L.P. Mayer et al., Abstract and Poster Presentation at the Endocrinology annual meeting in San Francisco, "Development of an Ovary-Intact Murine Model for the Study of Menopause-related Pathologies", June 2002.					
	AAH	GM Buss et al., Abstract and Poster Presentation, Presented at the Mountain West Society for Toxicology, September 20, 2001, "Steroidogenic Responsiveness of 4-Vinylcyclohexene Diepoxide (VCD-Induced Follicle-Deplete Murine Ovaries to Gonadotropin Stimulation In Vitro".					
	AAI	Hoyer and Mayer, "Background and Significance," Unpublished Summary, March 2002, pp. 1-7.					
	AAJ	Loretta P. Mayer et al., Poster Presentation at the Atherosclerosis, Thrombosis and Vascular Biology Meeting of the American Heart Association, Spring (March?) 2002.					
	AAK	In House Talk done By 10/30/01, entitled "Mouseopause: A model whose time has come.					
	AAL						
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